IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPEYSIDE MEDICAL, LLC, Plaintiff, v. MEDTRONIC COREVALVE, LLC; MEDTRONIC, INC. and MEDTRONIC PLC, Defendants.	Civil Action No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff Speyside Medical, LLC ("Speyside Medical"), for its Complaint against Defendants Medtronic Corevalve, LLC; Medtronic, Inc.; and Medtronic PLC (collectively, "Medtronic"), hereby alleges as follows:

PARTIES

1. Plaintiff Speyside Medical is a limited liability company organized under the laws of Delaware with a place of business at 592 Rosso Court, Pleasanton, California 94566.

2. Upon information and belief, Defendant Medtronic Corevalve, LLC is a limited liability company organized under the laws of Delaware with a place of business at 3576 Unocal Place, Fountaingrove, Santa Rosa, CA 954031. Upon information and belief, Medtronic Corevalve, LLC has designated Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808 as its registered agent for service of process.

3. Upon information and belief, Defendant Medtronic, Inc. is a corporation organized under the laws of Minnesota with a place of business at 710 Medtronic Parkway,

Minneapolis, MN 55432. Upon information and belief, Medtronic, Inc. has designated Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808 as its registered agent for service of process.

4. Upon information and belief, Defendant Medtronic PLC is a corporation organized under the laws of Ireland with a place of business at 20 Lower Hatch Street, Dublin 2, Ireland.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

7. Upon information and belief, Medtronic holds itself out as a single entity and its subsidiaries and affiliates are agents of each other and/or work in concert with each other with respect to the manufacture, regulatory approval, marketing, sale, importation and distribution of the Accused Products throughout the United States, including Delaware.

8. Upon information and belief, Medtronic has committed tortious acts of patent infringement and intends a future course of conduct that includes further acts of patent infringement in Delaware. Upon information and belief, Medtronic has made, used, sold, offered to sell, and/or imported, and continues to make, use, sell, offer for sale, and/or import in Delaware products that infringe, or are used to infringe, Speyside Medical's patents. Medtronic's infringing products include, for example, its Evolut™ and CoreValve™ transcatheter aortic valve replacement ("TAVR") lines of devices ("the Accused Products").

9. Upon information and belief, Medtronic has substantial, continuous, and systematic contacts with Delaware.

10. Upon information and belief, Medtronic is in the business of, among other things, manufacturing and selling medical devices and medical products. Upon information and belief, Medtronic, itself and through its subsidiaries, affiliates, and agents, manufactures, imports, markets, distributes and/or sells medical devices and medical products, including the Accused Products, throughout the United States, including Delaware.

11. Upon information and belief, Medtronic has distribution channels throughout the United States, including in Delaware. By advertising the Accused Products on the Medtronic website and without restriction to a particular geographic area, Medtronic has made clear that it intends to use Medtronic's national distribution channels to distribute and sell the Accused Products throughout the United States, including Delaware, which would have a substantial effect on Delaware. Medtronic has introduced the Accused Products into the stream of commerce with the knowledge, or reasonable expectation, that actual or potential users of such products and methods are located within Delaware.

12. This Court has personal jurisdiction over Medtronic Corevalve, LLC by virtue of, for example, (1) its organization in Delaware, (2) its continuous and systematic contacts with Delaware, (3) its registered agent for service of process in Delaware, (4) its acts of tortious patent infringement in Delaware, and (5) its sale of a substantial volume of medical devices and products in Delaware.

13. This Court has personal jurisdiction over Medtronic, Inc., by virtue of, for example, (1) its continuous and systematic contacts with Delaware, (2) its registered agent for service of process in Delaware, (3) its acts of tortious patent infringement in Delaware, and (4)

its sale of a substantial volume of medical devices and products in Delaware.

14. This Court has personal jurisdiction over Medtronic PLC by virtue of, for example, (1) its continuous and systematic contacts with the United States, including Delaware, (2) its acts of tortious patent infringement in Delaware, (3) its sale of a substantial volume of medical devices and products in Delaware, and (4) its conduct by, through and in concert with Medtronic Corevalve, LLC and Medtronic, Inc.

15. In the alternative, this Court has personal jurisdiction over Medtronic PLC under Rule 4(k)(2), Fed. R. Civ. P.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400 (b).

THE PATENTS-IN-SUIT

17. Speyside Medical is the owner of U.S. Patent Nos. 8,377,118 ("the '118 patent"); 9,445,897 ("the '897 patent"); 9,510,941 ("the '941 patent"); 9,603,708 ("the '708 patent"); and 10,449,040 ("the '040 patent") (collectively, the "patents-in-suit").

18. On February 19, 2013, the United States Patent and Trademark Office ("the Patent Office") duly and legally issued the '118 patent, entitled "Unstented Heart Valve With Formed In Place Support Structure." A true and correct copy of the '118 patent is attached hereto as Exhibit A.

19. On September 20, 2016, the Patent Office duly and legally issued the '897 patent, entitled "Prosthetic Implant Delivery Device With Introducer Catheter." A true and correct copy of the '897 patent is attached hereto as Exhibit B.

20. On December 6, 2016, the Patent Office duly and legally issued the '941 patent, entitled "Method Of Treating A Patient Using A Retrievable Transcatheter Prosthetic Heart

Valve." A true and correct copy of the '941 patent is attached hereto as Exhibit C.

21. On March 28, 2017, the Patent Office duly and legally issued the '708 patent, entitled "Low Crossing Profile Delivery Catheter For Cardiovascular Prosthetic Implant." A true and correct copy of the '708 patent is attached hereto as Exhibit D.

22. On October 22, 2019, the Patent Office duly and legally issued the '040 patent, entitled "Method of Treating a Patient Using a Retrievable Transcatheter Prosthetic Heart Valve." A true and correct copy of the '040 patent is attached hereto as Exhibit E.

23. The patents-in-suit relate to devices and methods used in valve replacement surgery, including TAVR surgery. A properly functioning aortic valve generally has thin leaflets of tissue that open and close to regulate blood flow when the heart beats. In some individuals, however, these leaflets can stiffen and cause a narrowing of the aortic valve. The narrowing of the valve can make it more difficult for the heart to pump blood to and from the body.

24. One method for replacing a diseased aortic valve is through open heart surgery. This typically requires stopping the heart and lungs and placing the patient on a heart and lung machine. The surgeon then opens the patient and replaces by hand the diseased aortic valve with an implant. Open heart surgery carries with it serious risks, including infection, stroke, and even death.

25. The new devices and methods covered by the patents-in-suit offer superior outcomes and reduced risk to patients in need of valve replacement surgery. Unlike open-heart surgery, the devices and methods allow a surgeon to replace a valve without the need to open the patient or place the patient on a heart or lung machine. Instead, the surgeon uses a catheter to deploy a new valve implant without stopping the patient's heart or lungs. The implant and

related deployment devices covered by the patents-in-suit have the smallest possible profile so that the smallest and least invasive catheter size may be used. The implant and related deployment devices also allow the surgeon to recapture and reposition the implant as necessary during surgery. The devices and methods covered by the patents-in-suit are the result of many years of research and development and significant expenditure of money and resources.

MEDTRONIC'S ACCUSED PRODUCTS AND METHODS

26. Upon information and belief, Medtronic makes, uses, imports, offers to sell, and/or sells Accused Products that infringe the patents-in-suit. Medtronic markets and sells the Accused Products under various trade names, including Evolut™ and CoreValve™. Upon information and belief, the Evolut™ platform is the latest generation of Medtronic's TAVR devices and is based on the design of the prior CoreValve™ platform. Upon information and belief, the Evolut™ platform includes at least the Evolut Pro+ System, the Evolut Pro System, and the Evolut R System.

27. Upon information and belief, Medtronic markets the Accused Products as recapturable and repositionable devices. Upon information and belief, Medtronic advertises that the Accused Products employ a self-expanding nitinol frame that enhances the ability of the device to conform to and seal the native annulus. Upon information and belief, Medtronic further states that the Accused Products employ strong porcine pericardial tissue, making them durable and allowing delivery of a low-profile device.

28. Upon information and belief, Medtronic has been aware of the patents-in-suit at all relevant times. For example, upon information and belief, employees of Medtronic met with employees of Direct Flow Medical Inc. ("Direct Flow"), the original assignee of the patents-in-suit, at least as early as 2006. At that time, Direct Flow presented information about Direct

Flow's business, product research and development, patent filings and patent strategy, including information about pending patent applications that subsequently led to the patents-in-suit. Upon information and belief, employees from Direct Flow and other representatives met with employees of Medtronic in 2007 and in subsequent years to discuss, among other things, Direct Flow's business and the patents-in-suit. Upon information and belief, based on these numerous meetings and the relevance of Direct Flow's business and the patents-in-suit to Medtronic's Accused Products, Medtronic has known or should have known of the patents-in-suit, and Medtronic's infringement of the patents-in-suit, at least since each of the patents-in-suit issued.

29. Medtronic has also known of the patents-in-suit and Medtronic's infringement of the patents-in-suit as of the filing of this Complaint.

30. Upon information and belief, Medtronic actively and intentionally encourages its customers, for example, hospitals and surgeons, to use the Accused Products according to certain methods and processes taught by Medtronic, for example, in its marketing materials, instructions for use and through its employees. Upon information and belief, Medtronic's customers employ the methods and processes taught by Medtronic when using the Accused Products.

COUNT I
INFRINGEMENT OF THE '118 PATENT

31. Speyside Medical incorporates by reference each and every allegation contained in the preceding Paragraphs as though fully set forth herein.

32. Speyside Medical owns all right, title, and interest in, including the right to sue and recover damages for infringement of the '118 patent.

33. Upon information and belief, Medtronic has been aware of the '118 patent at all relevant times.

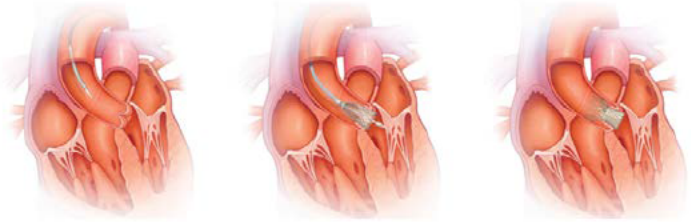
34. Medtronic has induced and continues to induce infringement of one or more

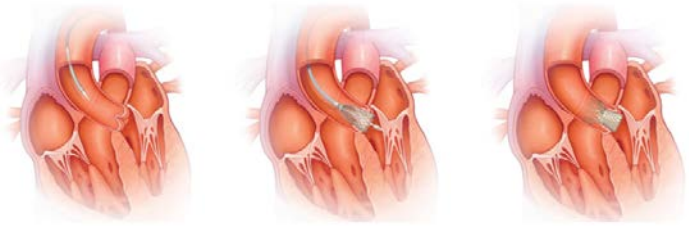
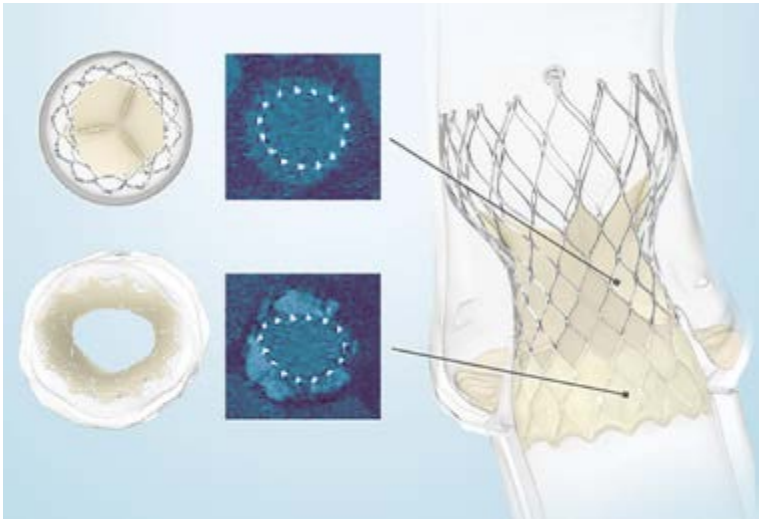
claims of the ‘118 patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Upon information and belief, Medtronic intentionally has encouraged and continues to encourage direct infringement by its customers with knowledge of the ‘118 patent and knowledge that its acts have encouraged and continue to encourage direct infringement, or while remaining willfully blind to the possibility that its inducing acts would cause infringement.

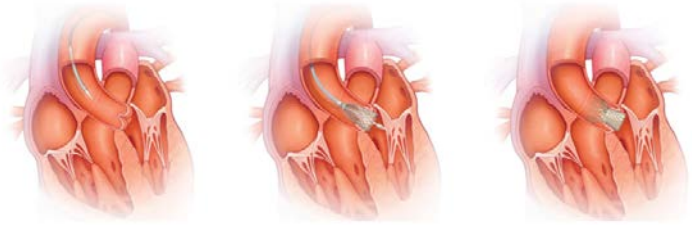
35. Upon information and belief, Medtronic specifically intends for customers to infringe the ’118 patent. Medtronic encourages infringement by customers at least by providing product support and instructions on how to use the Accused Products. For example, Medtronic provides “Instructions for Use” for each of the Accused Products on Medtronic’s website. *See, e.g.*, http://manuals.medtronic.com/manuals/main/en_US/home.

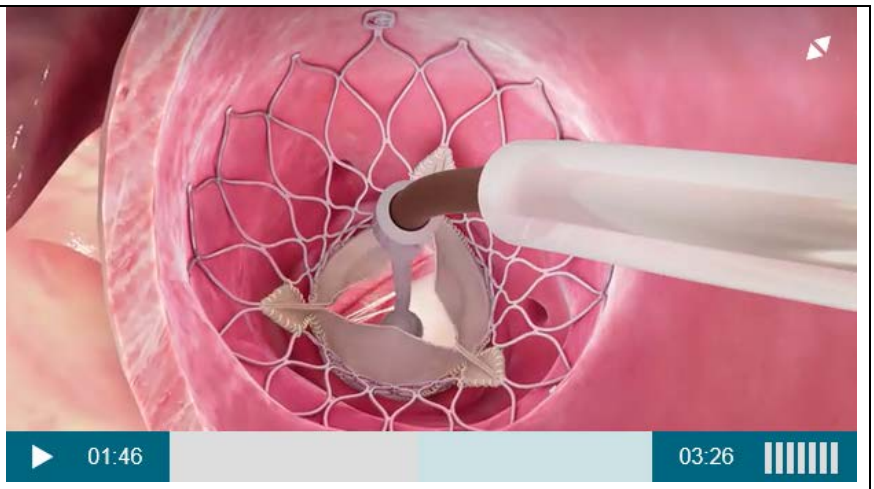
36. Medtronic has contributed to and continues to contribute to infringement of one or more claims of the ‘118 patent, including at least claim 1, in violation of 35 U.S.C. § 271(c) by selling, offering to sell and/or importing the Accused Products in the United States for use in practicing the processes claimed in the ‘118 patent. Upon information and belief, the use of the Accused Products constitutes a material part of the processes claimed in the ‘118 patent, and Medtronic has knowledge that this use is especially made or adapted for use in the infringement of the ‘118 patent. Upon information and belief, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing use.

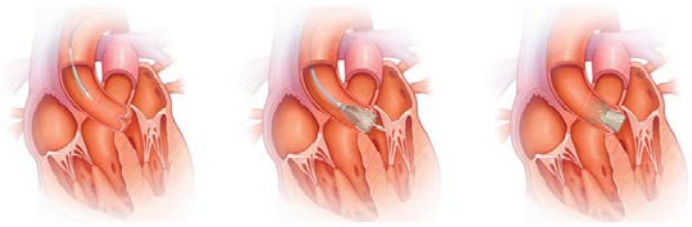
37. Upon information and belief, Medtronic’s customers have infringed and continue to infringe directly the ‘118 patent, including at least claim 1, either literally or under the doctrine of equivalents. The left side of the table below contains the language of claim 1 of the ‘118 patent, and the right side of the table contains quotations and images from marketing materials found on Medtronic’s website.

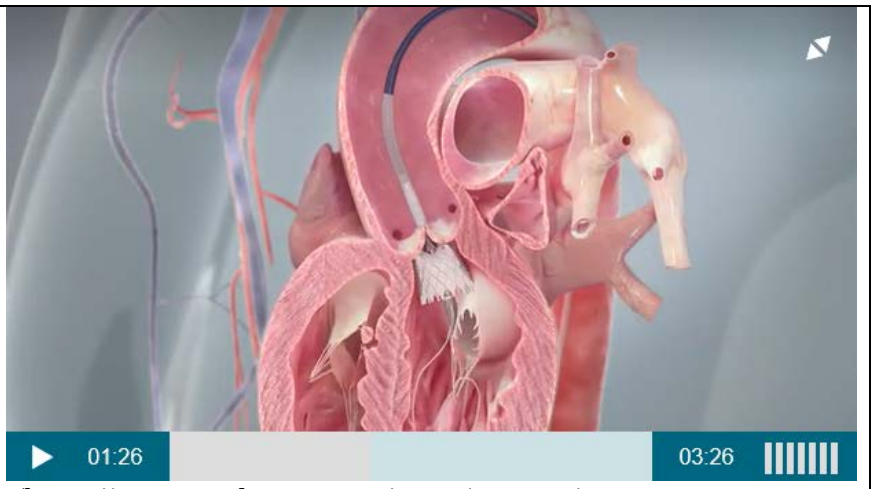
The '118 Patent	Medtronic Marketing Materials
1. A method for replacing a patient's native aortic heart valve in a heart, the method comprising:	Without conceding whether the preamble is a limitation of this claim, the quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a method for replacing a patient's native aortic heart valve in a heart. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).
delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating,	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating. "The bioprosthesis is manufactured by suturing 3 valve leaflets and an inner skirt, made from a single layer of porcine pericardium, onto a self-expanding, multi-level, radiopaque frame made of Nitinol. The bioprosthesis has a porcine pericardial tissue outer skirt (wrap), which is 1.5 cells in height and is sutured to the inflow section of the bioprosthesis. It is designed to replace the native or surgical bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical removal of the failed valve."

	(Evolut Pro+ System Instructions for Use, p. 2.) "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  "TAVR does not require open-heart surgery. Instead, with TAVR, the heart is accessed via an artery." (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).  (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-r.html).

the carrier element having proximal and distal ends, the replacement valve configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction;	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a carrier element having proximal and distal ends, the replacement valve configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). The video on Medtronic's website shows how the replacement valve is configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction:

	 (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve; expanding the carrier element from a collapsed delivery configuration to a first expanded configuration; using the carrier element to exclude the native aortic heart valve in the first expanded configuration, forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration; using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration;	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve; expanding the carrier element from a collapsed delivery configuration to a first expanded configuration; using the carrier element to exclude the native aortic heart valve in the first expanded configuration, forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration; using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."

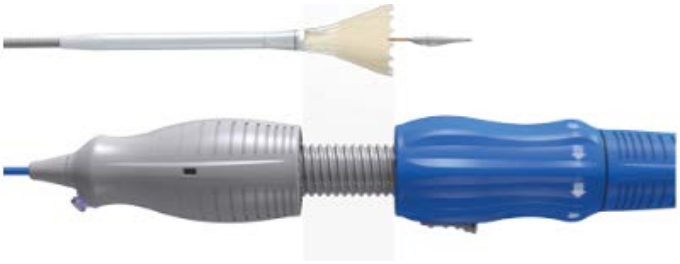
	 (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). "3. Advance the device through the valve. Perform an angiogram to confirm that the pigtail catheter is in position within the noncoronary cusp of the aortic root. Fluoroscopically identify the appropriate landmarks. 4. Position the catheter so that the bioprosthesis is at the optimal depth relative to the valve annulus. For surgical bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis. 5. To deploy the bioprosthesis, rotate the deployment knob in the direction of the arrows. The capsule retracts and exposes the bioprosthesis. Continue deploying the bioprosthesis in a controlled manner, adjusting valve position as necessary and noting the position of the radiopaque capsule marker band and paddle attachment." (Evolut Pro+ System Instructions for Use, p. 32.) The video on Medtronic's website shows positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve; expanding the carrier element from a collapsed delivery configuration to a first expanded configuration; using the carrier element to exclude the native aortic heart valve in the first expanded configuration, forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration; and using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration:

	 (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
evaluating the position of the carrier element; at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration, a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration;	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes evaluating the position of the carrier element; at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration, a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration. "6. Before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment, evaluate the bioprosthesis position. . . . 7. Either complete bioprosthesis deployment or initiate bioprosthesis recapture." (Evolut Pro+ System Instructions for Use, p. 32.) "The bioprosthesis is recapturable during deployment before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment. Deployment of the bioprosthesis can be attempted 3 times. If the bioprosthesis is recaptured a third time, it must be removed from the patient. 1. Rotate the deployment knob in the opposite direction of the arrows to recapture the bioprosthesis. A partially recaptured bioprosthesis can be repositioned or fully recaptured." (Evolut Pro+ System Instructions for Use, p. 33.) "CONTROL DURING DEPLOYMENT**:** The Evolut PRO+

delivery system:

- Assists in accurate positioning of the valve
- Features a 1:1 response for immediate feedback between the deployment knob and the movement of the capsule
- Provides you the option to recapture and reposition[FN] for more accurate placement.

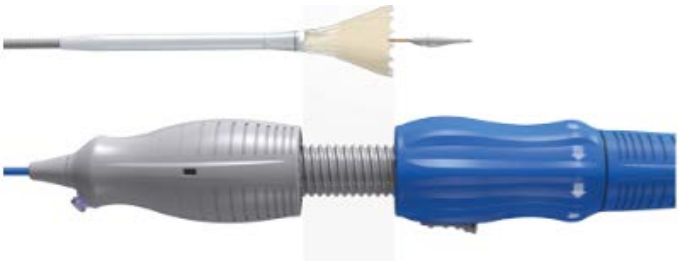
FN Up to 80% deployment. The valve can be partially or fully recaptured up to three times prior to the point of no recapture. Third attempt must be a complete recapture and retrieval from patient."

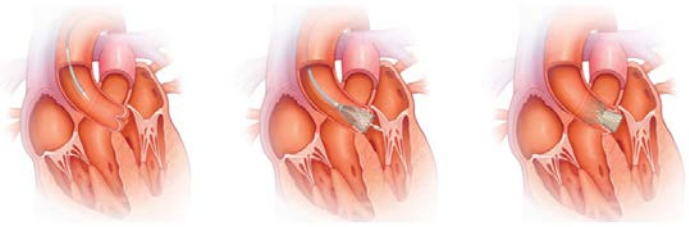


(https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro-plus.html).

The video on Medtronic's website shows that a length of the carrier element in the moveable configuration is substantially equal to or less than a length of the carrier element in the first expanded configuration:

	 (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve;	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve. "The bioprosthesis is recapturable during deployment before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment. Deployment of the bioprosthesis can be attempted 3 times. If the bioprosthesis is recaptured a third time, it must be removed from the patient. 1. Rotate the deployment knob in the opposite direction of the arrows to recapture the bioprosthesis. A partially recaptured bioprosthesis can be repositioned or fully recaptured." (Evolut Pro+ System Instructions for Use, p. 33.) "CONTROL DURING DEPLOYMENT**:** The Evolut PRO+ delivery system: • Assists in accurate positioning of the valve • Features a 1:1 response for immediate feedback between the deployment knob and the movement of the capsule • Provides you the option to recapture and reposition[FN] for more accurate placement. FN Up to 80% deployment. The valve can be partially or fully recaptured up to three times prior to the point of no recapture. Third attempt must be a complete recapture and retrieval from patient."

	 (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro-plus.html).
expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve, the proximal and distal ends of the carrier element being proximate opposing sides of the native aortic heart valve in the second expanded configuration; using the carrier element to exclude the native aortic heart valve in the second expanded configuration; forming a seal between the carrier element and one or more anatomical features in the second expanded configuration; and using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the second expanded configuration.	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve, the proximal and distal ends of the carrier element being proximate opposing sides of the native aortic heart valve in the second expanded configuration; using the carrier element to exclude the native aortic heart valve in the second expanded configuration; forming a seal between the carrier element and one or more anatomical features in the second expanded configuration; and using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the second expanded configuration. "4. Redeploy the bioprosthesis (Section 9.2.4, steps 5 and 6). 5. Either complete bioprosthesis redeployment or initiate bioprosthesis recapture. If the bioprosthesis has been recaptured 3 times, withdraw the recaptured bioprosthesis." (Evolut Pro+ System Instructions for Use, p. 33.) "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."



(https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).

The video on Medtronic's website shows expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve, the proximal and distal ends of the carrier element being proximate opposing sides of the native aortic heart valve in the second expanded configuration;
using the carrier element to exclude the native aortic heart valve in the second expanded configuration; forming a seal between the carrier element and one or more anatomical features in the second expanded configuration; and using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the second expanded configuration:

(https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)

38. Medtronic does not have a license or any other authority to practice the methods claimed in the '118 patent.

39. As a result of Medtronic's infringement of the '118 patent, Speyside Medical has suffered and will continue to suffer damages. Speyside Medical is entitled to recover from Medtronic the damages adequate to compensate for such infringement, which have yet to be determined.

COUNT II
INFRINGEMENT OF THE '897 PATENT

40. Speyside Medical incorporates by reference each and every allegation contained in the preceding Paragraphs as though fully set forth herein.

41. Speyside Medical owns all right, title, and interest in, including the right to sue and recover damages for infringement of the '897 patent.

42. Upon information and belief, Medtronic has been aware of the '897 patent at all relevant times.

43. Medtronic has induced and continues to induce infringement of one or more claims of the '897 patent, including at least claim 1, in violation of 35 U.S.C. § 271(b). Upon information and belief, Medtronic intentionally has encouraged and continues to encourage direct infringement by its customers with knowledge of the '897 patent and knowledge that its acts have encouraged and continue to encourage direct infringement, or while remaining willfully blind to the possibility that its inducing acts would cause infringement.

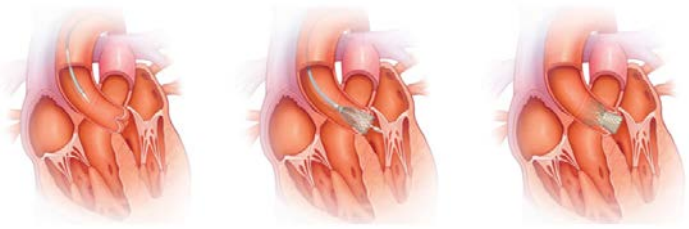
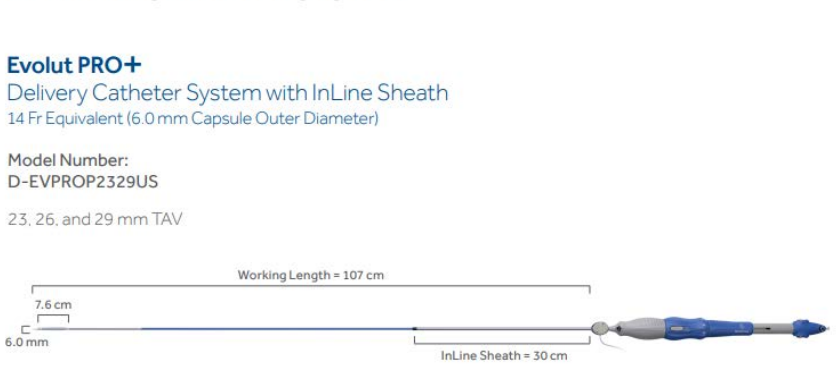
44. Upon information and belief, Medtronic specifically intends for customers to infringe the '897 patent. Medtronic encourages infringement by customers at least by providing product support and instructions on how to use the Accused Products. For example, Medtronic provides "Instructions for Use" for each of the Accused Products on Medtronic's website. *See, e.g.*, http://manuals.medtronic.com/manuals/main/en_US/home.

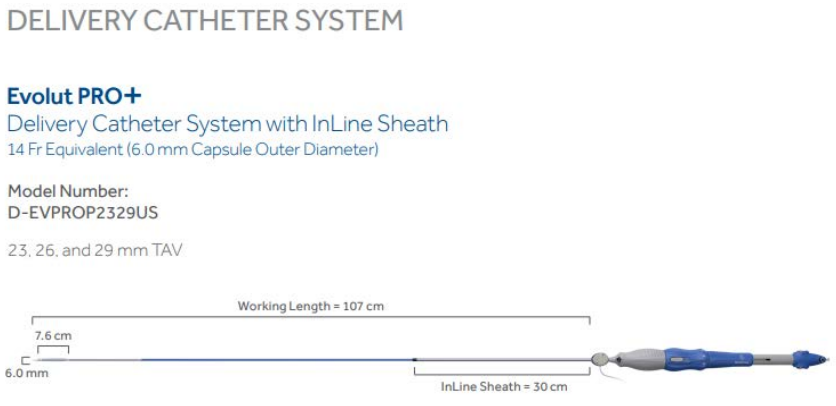
45. Medtronic has contributed to and continues to contribute to infringement of one or

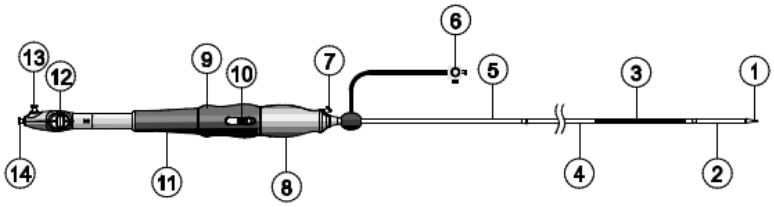
more claims of the '897 patent, including at least claim 1, in violation of 35 U.S.C. § 271(c) by selling, offering to sell and/or importing the Accused Products in the United States for use in practicing the processes claimed in the '897 patent. Upon information and belief, the use of the Accused Products constitutes a material part of the processes claimed in the '897 patent, and Medtronic has knowledge that this use is especially made or adapted for use in the infringement of the '897 patent. Upon information and belief, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing use.

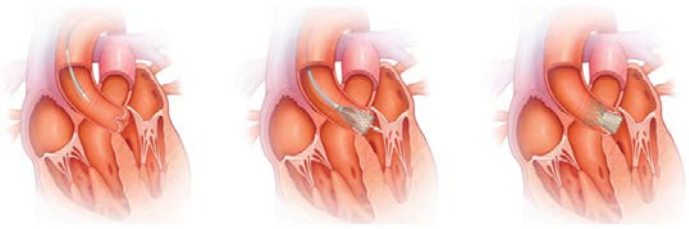
46. Upon information and belief, Medtronic's customers have infringed and continue to infringe directly the '897 patent, including at least claim 1, either literally or under the doctrine of equivalents. The left side of the table below contains the language of claim 1 of the '897 patent, and the right side of the table contains quotations and images from marketing materials found on Medtronic's website.

The '897 Patent	Medtronic Marketing Materials
1. A method of positioning a prosthetic implant within a heart, the method comprising:	Without conceding whether the preamble is a limitation of this claim, the quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a method of positioning a prosthetic implant within a heart. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."

	 (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).
advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system,	The image below, as well as Medtronic's description of the Accused Products on its website, shows that use of the Accused Products includes advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system.  (https://www.medtronic.com/content/dam/medtronic-com/products/cardiovascular/transcatheter-aortic-heart-valves/documents/evolut-pro-plus-product-specs.pdf). "The catheter facilitates the placement of the bioprosthesis within the annulus of the aortic valve. The catheter assembly is flexible and compatible with a 0.035 in (0.889 mm) guidewire. The distal (deployment) end of the system features an atraumatic, radiopaque catheter tip and a capsule that covers and maintains the bioprosthesis in a crimped position. The capsule includes a distal flare to enable the bioprosthesis to be partially or fully recaptured after partial deployment. A stability layer is fixed at the handle and extends down the outside of the catheter shaft. It provides a barrier between the retractable catheter and the introducer sheath and vessel walls, thus enabling the catheter to retract freely. An Evolut PRO+ inline sheath is assembled over the stability layer, which functions as a hemostatic introducer

	sheath and minimizes the access site size to the capsule diameter." (Evolut Pro+ System Instructions for Use, p. 3.) "1. Insert the device over the 0.035 in (0.889 mm) guidewire. Insert the catheter tip and capsule through the access site, while maintaining the Evolut PRO+ inline sheath tip against the proximal end of the capsule. Then, insert the Evolut PRO+ inline sheath through the access site, maintaining contact with the capsule. Maintain strict fluoroscopic surveillance of the guidewire in the LV. . . . 2. Under fluoroscopic guidance, advance the catheter over the guidewire to the aortic annulus. Do not rotate the catheter as it is advanced; rotating the handle does not rotate the capsule." (Evolut Pro+ System Instructions for Use, pp. 31-32.)
the delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter, wherein during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter, the introducer catheter comprising a hemostasis valve assembly at a proximal end of the introducer catheter;	The image below, as well as Medtronic's description of the Accused Products on its website, shows that use of the Accused Products includes delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter, wherein during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter, the introducer catheter comprising a hemostasis valve assembly at a proximal end of the introducer catheter.  (https://www.medtronic.com/content/dam/medtronic-com/products/cardiovascular/transcatheter-aortic-heart-valves/documents/evolut-pro-plus-product-specs.pdf). "The distal (deployment) end of the system features an

	atraumatic, radiopaque catheter tip and a capsule that covers and maintains the bioprosthesis in a crimped position." (Evolut Pro+ System Instructions for Use, p. 3.)  **Figure 5: Catheter** 1. Catheter tip 2. Capsule (Model D-EVPROP2329US: 18 Fr [6.0 mm] outer diameter [OD]; Model D-EVPROP34US: 22 Fr [7.33 mm] OD) 3. Catheter shaft 4. Stability layer 5. Model D-EVPROP2329US: 14 Fr equivalent Evolut PRO+ inline sheath (18 Fr [6.0 mm] OD); Model D-EVPROP34US: 18 Fr equivalent Evolut PRO+ inline sheath (22 Fr [7.33 mm] OD) (Evolut Pro+ System Instructions for Use, p. 4.)
the prosthetic valve being at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter; and	The image below, as well as Medtronic's description of the Accused Products on its website, shows that use of the Accused Products includes a prosthetic valve that is at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter. "The distal (deployment) end of the system features an atraumatic, radiopaque catheter tip and a capsule that covers and maintains the bioprosthesis in a crimped position." Evolut Pro+ System Instructions for Use, p. 3.  (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro-plus.html).
deploying the prosthetic valve.	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that the Accused Products include deploying the prosthetic valve. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the

	bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).

47. Medtronic does not have a license or any other authority to practice the methods claimed in the '897 patent.

48. As a result of Medtronic's infringement of the '897 patent, Speyside Medical has suffered and will continue to suffer damages. Speyside Medical is entitled to recover from Medtronic the damages adequate to compensate for such infringement, which have yet to be determined.

COUNT III
INFRINGEMENT OF THE '941 PATENT

49. Speyside Medical incorporates by reference each and every allegation contained in the preceding Paragraphs as though fully set forth herein.

50. Speyside Medical owns all right, title, and interest in, including the right to sue and recover damages for infringement of the '941 patent.

51. Upon information and belief, Medtronic has been aware of the '941 patent at all relevant times.

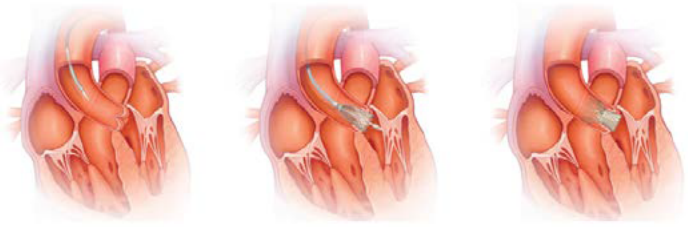
52. Medtronic has induced and continues to induce infringement of one or more claims of the ‘941 patent, including at least claim 17, in violation of 35 U.S.C. § 271(b). Upon information and belief, Medtronic intentionally has encouraged and continues to encourage direct infringement by its customers with knowledge of the ‘941 patent and knowledge that its acts have encouraged and continue to encourage direct infringement, or while remaining willfully blind to the possibility that its inducing acts would cause infringement.

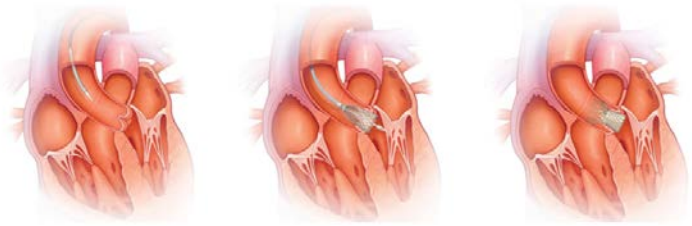
53. Upon information and belief, Medtronic specifically intends for customers to infringe the ’941 patent. Medtronic encourages infringement by customers at least by providing product support and instructions on how to use the Accused Products. For example, Medtronic provides “Instructions for Use” for each of the Accused Products on Medtronic’s website. *See, e.g.*, http://manuals.medtronic.com/manuals/main/en_US/home.

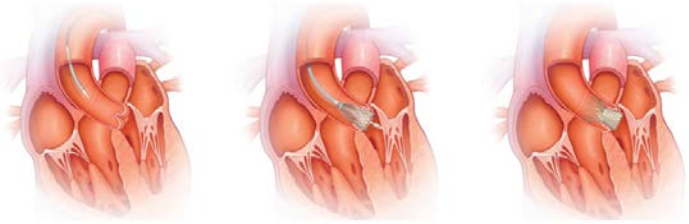
54. Medtronic has contributed to and continues to contribute to infringement of one or more claims of the ‘941 patent, including at least claim 17, in violation of 35 U.S.C. § 271(c) by selling, offering to sell and/or importing the Accused Products in the United States for use in practicing the processes claimed in the ‘941 patent. Upon information and belief, the use of the Accused Products constitutes a material part of the processes claimed in the ‘941 patent, and Medtronic has knowledge that this use is especially made or adapted for use in the infringement of the ‘941 patent. Upon information and belief, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing use.

55. Upon information and belief, Medtronic’s customers have infringed and continue to infringe directly the ‘941 patent, including at least claim 17, either literally or under the doctrine of equivalents. The left side of the table below contains the language of claim 17 of the ‘941 patent, and the right side of the table contains quotations and images from marketing

materials found on Medtronic's website.

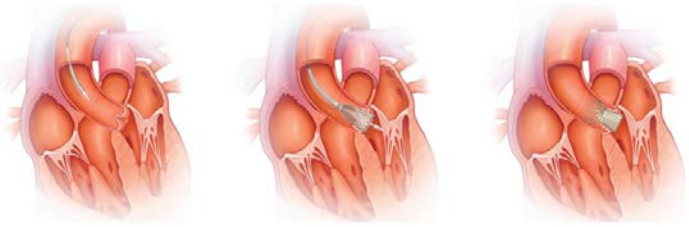
The '941 Patent	Medtronic Marketing Materials
17. A method for replacing a patient's native heart valve, the method comprising:	Without conceding whether the preamble is a limitation of this claim, the quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a method for replacing a patient's native heart valve. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).
delivering an expandable carrier element and a replacement valve endovascularly to a vicinity of the native heart valve; and	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes delivering an expandable carrier element and a replacement valve endovascularly to a vicinity of the native heart valve. "The bioprosthesis is manufactured by suturing 3 valve leaflets and an inner skirt, made from a single layer of porcine pericardium, onto a self-expanding, multi-level, radiopaque frame made of Nitinol. The bioprosthesis has a porcine pericardial tissue outer skirt (wrap), which is 1.5 cells in height and is sutured to the inflow section of the bioprosthesis. It is designed to replace the native or surgical bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical

	removal of the failed valve." (Evolut Pro+ System Instructions for Use, p. 2.) "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). "1. Insert the device over the 0.035 in (0.889 mm) guidewire. Insert the catheter tip and capsule through the access site, while maintaining the Evolut PRO+ inline sheath tip against the proximal end of the capsule. Then, insert the Evolut PRO+ inline sheath through the access site, maintaining contact with the capsule. Maintain strict fluoroscopic surveillance of the guidewire in the LV. . . . 2. Under fluoroscopic guidance, advance the catheter over the guidewire to the aortic annulus. Do not rotate the catheter as it is advanced; rotating the handle does not rotate the capsule. . . . 3. Advance the device through the valve. Perform an angiogram to confirm that the pigtail catheter is in position within the noncoronary cusp of the aortic root. Fluoroscopically identify the appropriate landmarks. 4. Position the catheter so that the bioprosthesis is at the optimal depth relative to the valve annulus. For surgical bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis. "

	(Evolut Pro+ System Instructions for Use, pp. 31-32.)
expanding the carrier element from a collapsed delivery configuration to an expanded configuration to secure the carrier element in the vicinity of the native heart valve,	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes expanding the carrier element from a collapsed delivery configuration to an expanded configuration to secure the carrier element in the vicinity of the native heart valve. "3. Advance the device through the valve. Perform an angiogram to confirm that the pigtail catheter is in position within the noncoronary cusp of the aortic root. Fluoroscopically identify the appropriate landmarks. 4. Position the catheter so that the bioprosthesis is at the optimal depth relative to the valve annulus. For surgical bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis. 5. To deploy the bioprosthesis, rotate the deployment knob in the direction of the arrows. The capsule retracts and exposes the bioprosthesis. Continue deploying the bioprosthesis in a controlled manner, adjusting valve position as necessary and noting the position of the radiopaque capsule marker band and paddle attachment." (Evolut Pro+ System Instructions for Use, p. 32.) "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-

	professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). The video on Medtronic's website shows that the carrier element is expanded from a collapsed delivery configuration to an expanded configuration to secure the carrier element in the vicinity of the native heart valve:   (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
wherein during expansion of the carrier element, a distal end of the carrier element is expanded prior to a proximal end of the carrier element being expanded,	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes during expansion of the carrier element, a distal end of the carrier element is expanded prior to a proximal end of the carrier element being expanded. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and

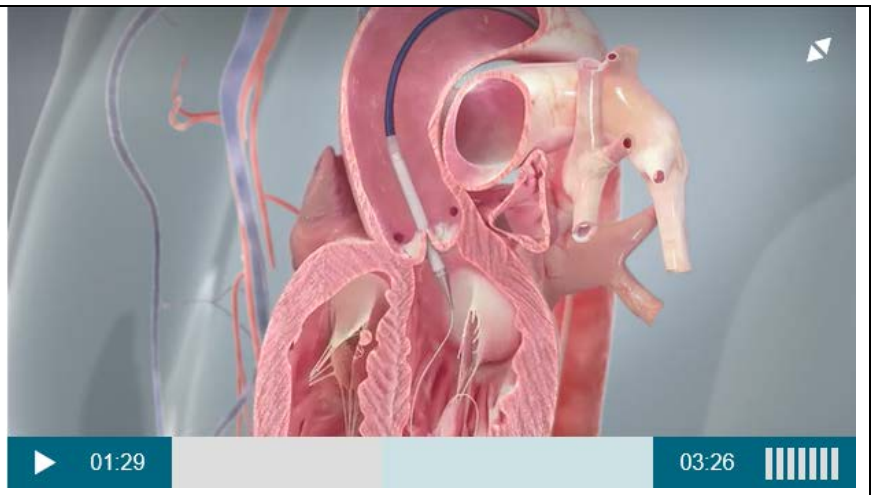
positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."

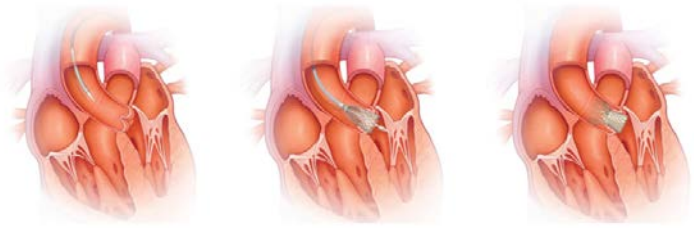
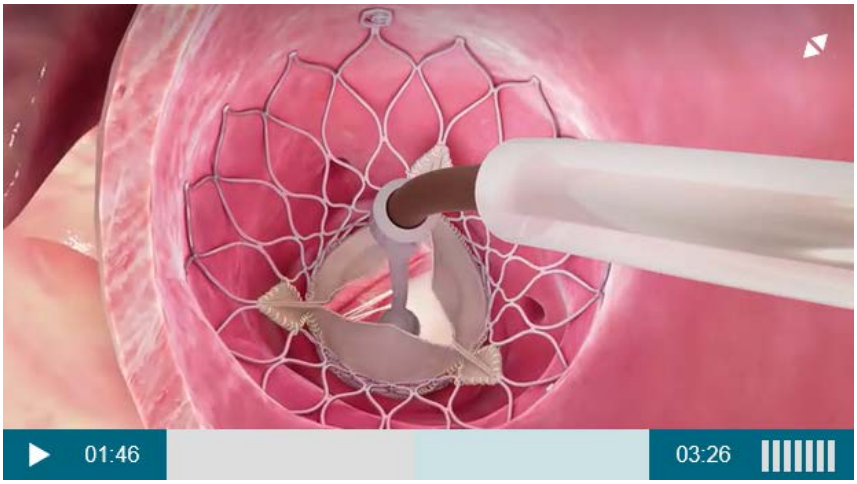


(https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).

The video on Medtronic's website shows that during expansion of the carrier element, a distal end of the carrier element is expanded prior to a proximal end of the carrier element being expanded:

	 (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
the proximal end of the carrier element being expanded without urging the proximal end of the carrier element toward the distal end of the carrier element,	The quotation below, as well as Medtronic's description of the Accused Products on its website, shows that use of the Accused Products includes the proximal end of the carrier element being expanded without urging the proximal end of the carrier element toward the distal end of the carrier element. "The Evolut PRO self-expanding transcatheter aortic valve features a unique valve design with an outer wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing performance." (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro.html). The video on Medtronic's website shows that the proximal end of the carrier element is expanded without urging the proximal end of the carrier element toward the distal end of the carrier element:

	  (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
wherein the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction during the expansion of the carrier element, after expanding the distal end of the carrier element, and prior to expanding the proximal end of the carrier element.	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes wherein the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction during the expansion of the carrier element, after expanding the distal end of the carrier element, and prior to expanding the proximal end of the carrier element. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded

	within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). The video on Medtronic's website shows how the replacement valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the replacement valve in a second direction during the expansion of the carrier element, after expanding the distal end of the carrier element, and prior to expanding the proximal end of the carrier element:  (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)

56. Medtronic does not have a license or any other authority to practice the methods claimed in the '941 patent.

57. As a result of Medtronic's infringement of the '941 patent, Speyside Medical has

suffered and will continue to suffer damages. Speyside Medical is entitled to recover from Medtronic the damages adequate to compensate for such infringement, which have yet to be determined.

COUNT IV
INFRINGEMENT OF THE '708 PATENT

58. Speyside Medical incorporates by reference each and every allegation contained in the preceding Paragraphs as though fully set forth herein.

59. Speyside Medical owns all right, title, and interest in, including the right to sue and recover damages for infringement of the '708 patent.

60. Medtronic has infringed and continues to infringe directly one or more claims of the '708 patent, including at least claim 21, in violation of 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling the Accused Products in Delaware and/or elsewhere in the United States.

61. Upon information and belief, Medtronic has been aware of the '708 patent at all relevant times.

62. Medtronic has induced and continues to induce infringement of one or more claims of the '708 patent, including at least claim 21, in violation of 35 U.S.C. § 271(b). Upon information and belief, Medtronic intentionally has encouraged and continues to encourage direct infringement by its customers with knowledge of the '708 patent and knowledge that its acts have encouraged and continue to encourage direct infringement, or while remaining willfully blind to the possibility that its inducing acts would cause infringement.

63. Upon information and belief, Medtronic specifically intends for customers to infringe the '708 patent. Medtronic encourages infringement by customers at least by providing product support and instructions on how to use the Accused Products. For example,

Medtronic provides "Instructions for Use" for each of the Accused Products on Medtronic's website. *See, e.g.*, http://manuals.medtronic.com/manuals/main/en_US/home.

64. Medtronic has contributed to and continues to contribute to infringement of one or more claims of the '708 patent, including at least claim 21, in violation of 35 U.S.C. § 271(c) by selling, offering to sell and/or importing the Accused Products in the United States. Upon information and belief, the use of the Accused Products constitutes a material part of the devices claimed in the '708 patent, and Medtronic has knowledge that the Accused Products are especially made or adapted for use in the infringement of the '708 patent. Upon information and belief, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing use.

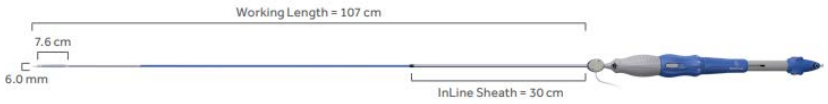
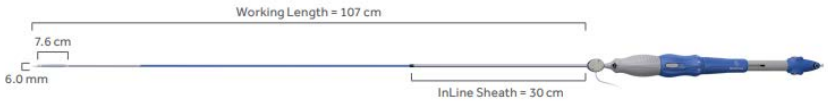
65. Medtronic has infringed and continues to infringe one or more claims of the '708 patent, including at least claim 21, in violation of 35 U.S.C. § 271(f) by supplying the Accused Products or causing the Accused Products to be supplied in or from the United States. Upon information and belief, the Accused Products constitute all or a substantial portion of the devices claimed in the '708 patent. Upon information and belief, the Accused Products are uncombined in whole or part, in such manner as to actively encourage their combination outside of the United States in a manner that would infringe the '708 patent if such combination occurred within the United States.

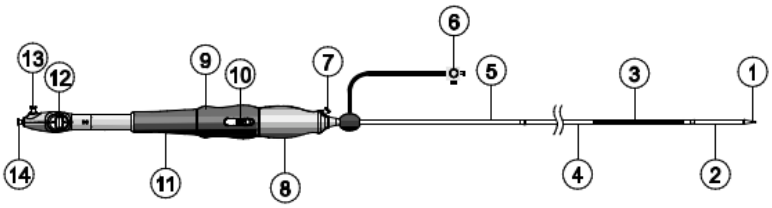
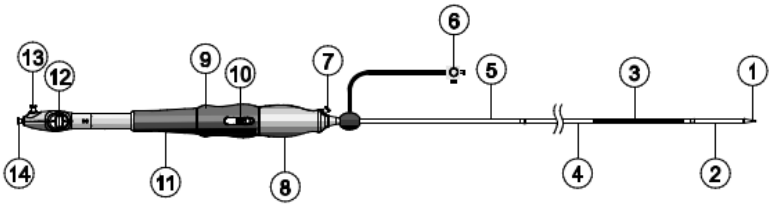
66. Medtronic has infringed and continues to infringe one or more claims of the '708 patent, including at least claim 21, in violation of 35 U.S.C. § 271(f) by supplying the Accused Products or causing the Accused Products to be supplied in or from the United States. Upon information and belief, the Accused Products are especially made or especially adapted for use in the devices claimed in the '708 patent. Upon information and belief, the Accused Products

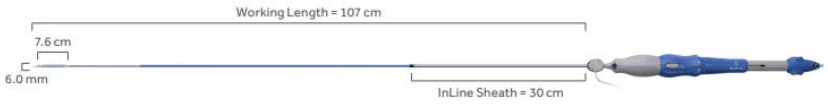
are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, the Accused Products are uncombined in whole or part, in a manner that would infringe the '708 patent if such combination occurred within the United States. Upon information and belief, Medtronic knows that the Accused Products are made or adapted in this manner and intends for them to be combined outside of the United States in a manner that would infringe the '708 patent if such combination occurred within the United States.

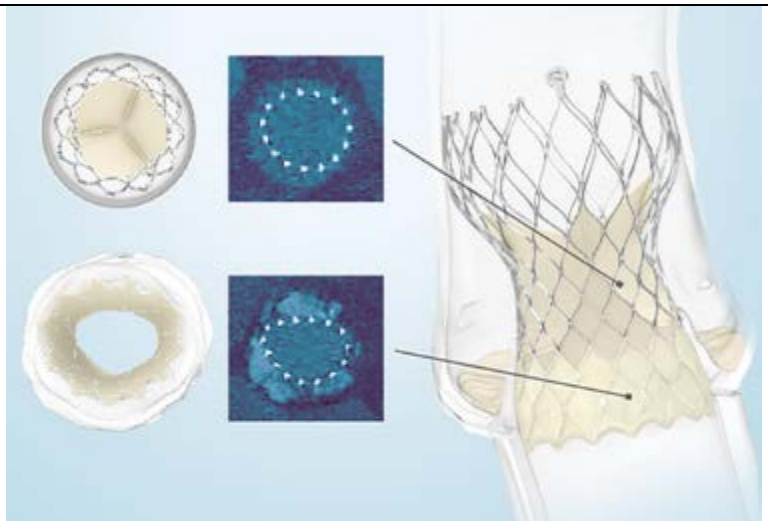
67. Upon information and belief, Medtronic's customers have infringed and continue to infringe directly the '708 patent, including at least claim 21, either literally or under the doctrine of equivalents. The left side of the table below contains the language of claim 21 of the '708 patent, and the right side of the table contains quotations and images from marketing materials found on Medtronic's website.

The '708 Patent	Medtronic Marketing Materials
21. A delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure, wherein the delivery catheter comprises:	Without conceding whether the preamble is a limitation of this claim, the image below, as well as Medtronic's description of the Accused Products on its website, shows that the Accused Products are a delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure. "The Medtronic Evolut™ PRO+ system is a recapturable transcatheter aortic valve replacement system, which includes the Evolut PRO+ transcatheter aortic valve (bioprosthesis), the delivery catheter system (catheter), and the loading system (LS). . . . It is designed to replace the native or surgical bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical removal of the failed valve." (Evolut Pro+ System Instructions for Use, p. 2.)

	DELIVERY CATHETER SYSTEM **Evolut PRO+** Delivery Catheter System with InLine Sheath 14 Fr Equivalent (6.0 mm Capsule Outer Diameter) Model Number: D-EVPROP2329US 23, 26, and 29 mm TAV  (https://www.medtronic.com/content/dam/medtronic-com/products/cardiovascular/transcatheter-aortic-heart-valves/documents/evolut-pro-plus-product-specs.pdf).
an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less; and	The image below, as well as Medtronic's description of the Accused Products on its website, shows that the Accused Products include an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less. DELIVERY CATHETER SYSTEM **Evolut PRO+** Delivery Catheter System with InLine Sheath 14 Fr Equivalent (6.0 mm Capsule Outer Diameter) Model Number: D-EVPROP2329US 23, 26, and 29 mm TAV  (https://www.medtronic.com/content/dam/medtronic-com/products/cardiovascular/transcatheter-aortic-heart-valves/documents/evolut-pro-plus-product-specs.pdf).

	 **Figure 5: Catheter** 1. Catheter tip 2. Capsule (Model D-EVPROP2329US: 18 Fr [6.0 mm] outer diameter [OD]; Model D-EVPROP34US: 22 Fr [7.33 mm] OD) 3. Catheter shaft 4. Stability layer 5. Model D-EVPROP2329US: 14 Fr equivalent Evolut PRO+ inline sheath (18 Fr [6.0 mm] OD); Model D-EVPROP34US: 18 Fr equivalent Evolut PRO+ inline sheath (22 Fr [7.33 mm] OD) (Evolut Pro+ System Instructions for Use, p. 4.)
a cardiovascular prosthetic implant loaded within the distal end of the catheter body,	The image below, as well as Medtronic's description of the Accused Products on its website, shows that the Accused Products include a cardiovascular prosthetic implant loaded within the distal end of the catheter body. "The distal (deployment) end of the system features an atraumatic, radiopaque catheter tip and a capsule that covers and maintains the bioprosthesis in a crimped position." (Evolut Pro+ System Instructions for Use, p. 3.)  **Figure 5: Catheter** 1. Catheter tip 2. Capsule (Model D-EVPROP2329US: 18 Fr [6.0 mm] outer diameter [OD]; Model D-EVPROP34US: 22 Fr [7.33 mm] OD) 3. Catheter shaft 4. Stability layer 5. Model D-EVPROP2329US: 14 Fr equivalent Evolut PRO+ inline sheath (18 Fr [6.0 mm] OD); Model D-EVPROP34US: 18 Fr equivalent Evolut PRO+ inline sheath (22 Fr [7.33 mm] OD) (Evolut Pro+ System Instructions for Use, p. 4.)

	DELIVERY CATHETER SYSTEM **Evolut PRO+** Delivery Catheter System with InLine Sheath 14 Fr Equivalent (6.0 mm Capsule Outer Diameter) Model Number: D-EVPROP2329US 23, 26, and 29 mm TAV  (https://www.medtronic.com/content/dam/medtronic-com/products/cardiovascular/transcatheter-aortic-heart-valves/documents/evolut-pro-plus-product-specs.pdf).
wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure.	The images below, as well as Medtronic's description of the Accused Products on its website, show that the Accused Products include a cardiovascular prosthetic implant that comprises a support structure and a natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure. "The bioprosthesis is manufactured by suturing 3 valve leaflets and an inner skirt, made from a single layer of porcine pericardium, onto a self-expanding, multi-level, radiopaque frame made of Nitinol. The bioprosthesis has a porcine pericardial tissue outer skirt (wrap), which is 1.5 cells in height and is sutured to the inflow section of the bioprosthesis. It is designed to replace the native or surgical bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical removal of the failed valve." (Evolut Pro+ System Instructions for Use, p. 2.)

	 (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-r.html).

68. Medtronic does not have a license or any other authority to practice the methods claimed in the '708 patent.

69. As a result of Medtronic's infringement of the '708 patent, Speyside Medical has suffered and will continue to suffer damages. Speyside Medical is entitled to recover from Medtronic the damages adequate to compensate for such infringement, which have yet to be determined.

COUNT V
INFRINGEMENT OF THE '040 PATENT

70. Speyside Medical incorporates by reference each and every allegation contained in the preceding Paragraphs as though fully set forth herein.

71. Speyside Medical owns all right, title, and interest in, including the right to sue and recover damages for infringement of the '040 patent.

72. Upon information and belief, Medtronic has been aware of the '040 patent at all relevant times.

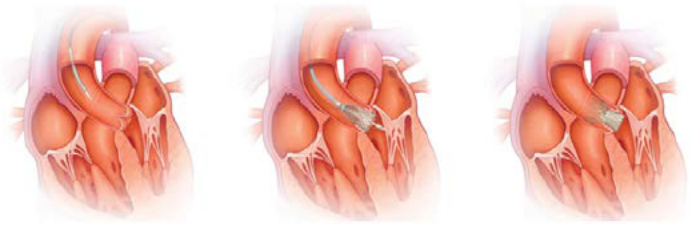
73. Medtronic has induced and continues to induce infringement of one or more claims of the ‘040 patent, including at least claim 7, in violation of 35 U.S.C. § 271(b). Upon information and belief, Medtronic intentionally has encouraged and continues to encourage direct infringement by its customers with knowledge of the ‘040 patent and knowledge that its acts have encouraged and continue to encourage direct infringement, or while remaining willfully blind to the possibility that its inducing acts would cause infringement.

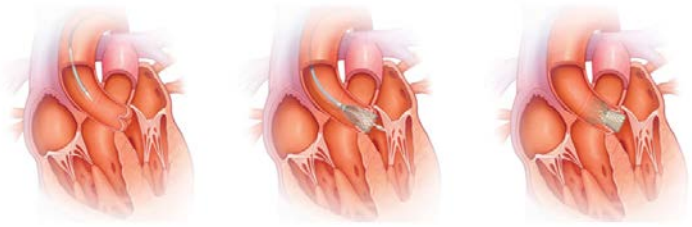
74. Upon information and belief, Medtronic specifically intends for customers to infringe the ’040 patent. Medtronic encourages infringement by customers at least by providing product support and instructions on how to use the Accused Products. For example, Medtronic provides “Instructions for Use” for each of the Accused Products on Medtronic’s website. *See, e.g.*, http://manuals.medtronic.com/manuals/main/en_US/home.

75. Medtronic has contributed to and continues to contribute to infringement of one or more claims of the ‘040 patent, including at least claim 7, in violation of 35 U.S.C. § 271(c) by selling, offering to sell and/or importing the Accused Products in the United States for use in practicing the processes claimed in the ‘040 patent. Upon information and belief, the use of the Accused Products constitutes a material part of the processes claimed in the ‘040 patent, and Medtronic has knowledge that this use is especially made or adapted for use in the infringement of the ‘040 patent. Upon information and belief, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing use.

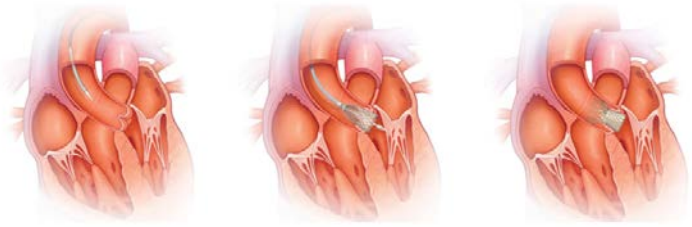
76. Upon information and belief, Medtronic’s customers have infringed and continue to infringe directly the ‘040 patent, including at least claim 7, either literally or under the doctrine of equivalents. The left side of the table below contains the language of claim 7 of the ‘040 patent, and the right side of the table contains quotations and images from marketing

materials found on Medtronic's website.

The '040 Patent	Medtronic Marketing Materials
7. A method of treating a patient, comprising:	Without conceding whether the preamble is a limitation of this claim, the quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes a method of treating a patient. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).
translumenally advancing a prosthetic valve to a position proximate a native valve of the heart; and	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes translumenally advancing a prosthetic valve to a position proximate a native valve of the heart. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."

	 (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). "1. Insert the device over the 0.035 in (0.889 mm) guidewire. Insert the catheter tip and capsule through the access site, while maintaining the Evolut PRO+ inline sheath tip against the proximal end of the capsule. Then, insert the Evolut PRO+ inline sheath through the access site, maintaining contact with the capsule. Maintain strict fluoroscopic surveillance of the guidewire in the LV. . . . 2. Under fluoroscopic guidance, advance the catheter over the guidewire to the aortic annulus. Do not rotate the catheter as it is advanced; rotating the handle does not rotate the capsule. . . . 3. Advance the device through the valve. Perform an angiogram to confirm that the pigtail catheter is in position within the noncoronary cusp of the aortic root. Fluoroscopically identify the appropriate landmarks. 4. Position the catheter so that the bioprosthesis is at the optimal depth relative to the valve annulus. For surgical bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis. " (Evolut Pro+ System Instructions for Use, pp. 31-32.)
deploying the prosthetic valve at the native valve from a collapsed delivery configuration to an expanded configuration, a distal end of the prosthetic valve being expanded prior to a proximal end of the prosthetic valve being expanded;	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes deploying the prosthetic valve at the native valve from a collapsed delivery configuration to an expanded configuration, a distal end of the prosthetic valve being expanded prior to a proximal end of the prosthetic valve being expanded. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the

bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."

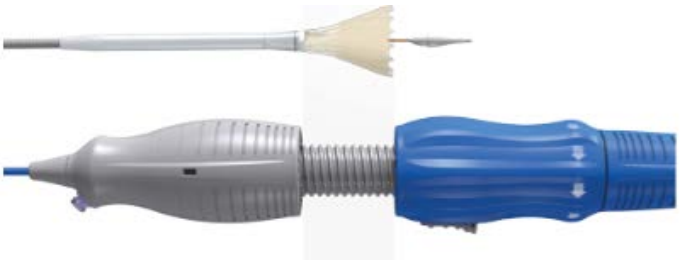


(https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html).

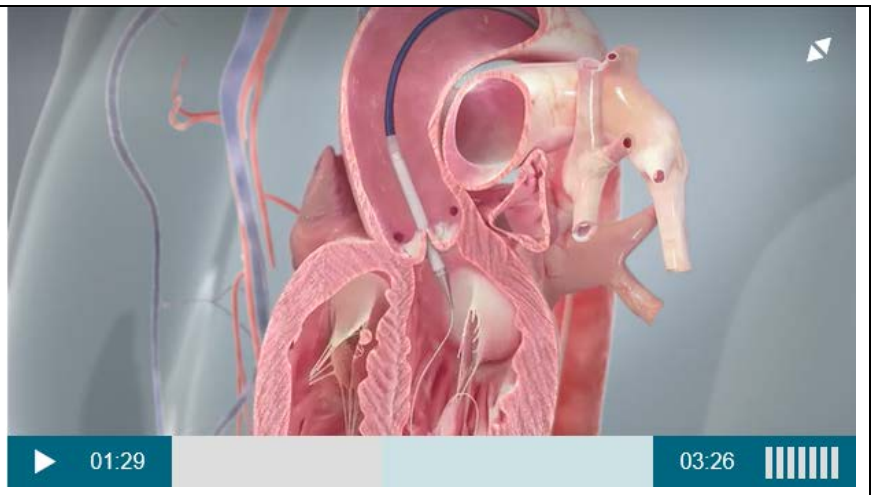
"5. To deploy the bioprosthesis, rotate the deployment knob in the direction of the arrows. The capsule retracts and exposes the bioprosthesis. Continue deploying the bioprosthesis in a controlled manner, adjusting valve position as necessary and noting the position of the radiopaque capsule marker band and paddle attachment."

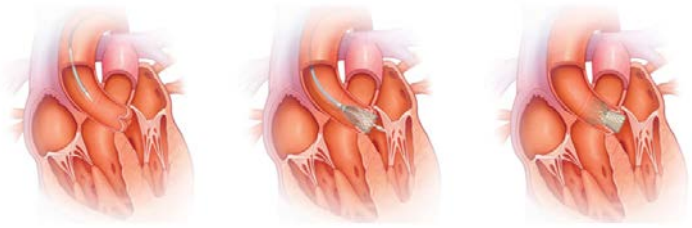
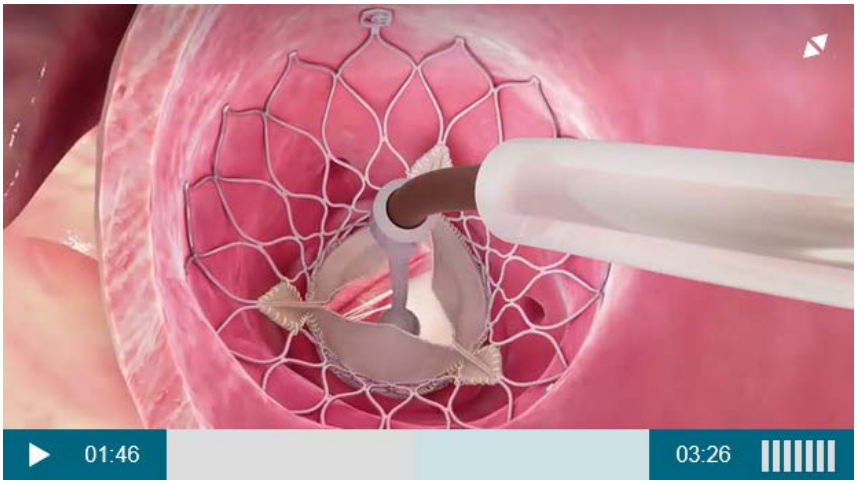
(Evolut Pro+ System Instructions for Use, p. 32.)

The video on Medtronic's website shows that a distal end of the prosthetic valve is expanded prior to a proximal end of the prosthetic valve being expanded:

	 (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
testing a performance characteristic of the prosthetic valve; at least partially reversing the deployment of the prosthetic valve; repositioning the prosthetic valve; and re-deploying the prosthetic valve,	The quotation and image below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes testing a performance characteristic of the prosthetic valve; at least partially reversing the deployment of the prosthetic valve; repositioning the prosthetic valve; and re-deploying the prosthetic valve. "CONTROL DURING DEPLOYMENT**:** The Evolut PRO+ delivery system: • Assists in accurate positioning of the valve • Features a 1:1 response for immediate feedback between the deployment knob and the movement of the capsule • Provides you the option to recapture and reposition[FN] for more accurate placement. FN Up to 80% deployment. The valve can be partially or fully recaptured up to three times prior to the point of no recapture. Third attempt must be a complete recapture and retrieval from patient."  (https://www.medtronic.com/us-en/healthcare-

	professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro-plus.html). "6. Before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment, evaluate the bioprosthesis position. . . . 7. Either complete bioprosthesis deployment or initiate bioprosthesis recapture." (Evolut Pro+ System Instructions for Use, p. 32.) "The bioprosthesis is recapturable during deployment before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment. Deployment of the bioprosthesis can be attempted 3 times. If the bioprosthesis is recaptured a third time, it must be removed from the patient. 1. Rotate the deployment knob in the opposite direction of the arrows to recapture the bioprosthesis. A partially recaptured bioprosthesis can be repositioned or fully recaptured." (Evolut Pro+ System Instructions for Use, p. 33.)
wherein the prosthetic valve does not include an interlocking locking mechanism, and	The quotation below, as well as Medtronic's description of the Accused Products on its website, shows that use of the Accused Products includes a prosthetic valve does not include an interlocking locking mechanism. "The Evolut PRO self-expanding transcatheter aortic valve features a unique valve design with an outer wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing performance." (https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/transcatheter-aortic-heart-valves/evolut-pro.html).

	  (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)
wherein the prosthetic valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve, after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve.	The quotation and images below, as well as Medtronic's description of the Accused Products on its website, show that use of the Accused Products includes the prosthetic valve preventing the flow of blood through the valve in a first direction and allowing the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve, after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve. "Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve; the middle image below shows a partially expanded valve. When deployment is complete, the bioprosthetic valve is fully expanded

	within the diseased native valve. After testing the new valve function, the physician removes the catheter and closes the incision."  (https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html). The video on Medtronic's website shows how the prosthetic valve prevents the flow of blood through the valve in a first direction and allows the flow of blood through the prosthetic valve in a second direction during the expansion of the prosthetic valve, after expanding the distal end of the prosthetic valve, and prior to expanding the proximal end of the prosthetic valve:  (https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement/about/tavr-procedure.html)

77. Medtronic does not have a license or any other authority to practice the methods claimed in the '040 patent.

78. As a result of Medtronic's infringement of the '040 patent, Speyside Medical has

suffered and will continue to suffer damages. Speyside Medical is entitled to recover from Medtronic the damages adequate to compensate for such infringement, which have yet to be determined.

JURY DEMAND

Pursuant to Rule 38(b), Fed. R. Civ. P., Speyside Medical respectfully demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Speyside Medical requests that judgment be entered in favor of Speyside Medical and against Medtronic as follows:

A. That Medtronic has infringed and is infringing the patents-in-suit;

B. That Speyside Medical be awarded damages under 35 U.S.C. § 284 in an amount sufficient to compensate it for infringement by Medtronic, including, but not limited to, a reasonable royalty, together with pre-judgment and post-judgment interest, and costs;

C. That this case be declared exceptional pursuant to 35 U.S.C. § 285 and that Speyside Medical be awarded its reasonable attorneys' fees, litigation expenses and expert witness fees, and costs;

D. That Speyside Medical be awarded an accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court's entry of judgment, and ongoing royalty through the life of the patents;

E. That Speyside Medical be awarded such other relief as this Court or a jury may deem proper and just under the circumstances.

Respectfully submitted,

Dated: March 13, 2020

/s/ John C. Phillips, Jr.

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